AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A composition for oral administration comprising a fixed dose combination of a first solid composition containing fenofibrate as the active substance and a second solid composition containing an HMG-CoA reductase inhibitor as the active substance, wherein the first and the second composition are present in separate layers ~~entities~~ in a single solid dosage form.

2. (Currently Amended) The composition according to claim 1, wherein the first solid composition ~~is in the form of~~ comprises granulate, granules, grains, beads or pellets.

3. (Currently Amended) The composition according to claim 1, wherein the second solid composition ~~is in the form of~~ comprises granulate, granules, grains, beads or pellets.

4. (Previously Presented) The composition according to claim 3, wherein the granules, granulate, grains, beads or pellets are entero-coated.

5. (Previously Presented) The composition according to claim 3, wherein the granules, granulate, grains, beads or pellets are coated with a protective coating.

6. (Previously Presented) The composition according to claim 1 in the form of a capsule or a sachet.

7. (Previously Presented) The composition according to claim 1 in the form of a tablet.

8. (Canceled)

9. (Previously Presented) The composition according to claim 8, wherein a layer comprising the first composition is separated from a layer comprising the second composition by an intermediate, inactive layer.

10. (Previously Presented) The composition according to claim 1, wherein the HMG-CoA reductase inhibitor is a statin selected from the group consisting of atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin, fluvastatin and pitavastatin.

11. (Withdrawn) The composition according to claim 10, wherein the HMG-CoA reductase inhibitor is simvastatin.

12. (Withdrawn) The composition according to claim 11 comprising a fixed dose combination selected from the group consisting of simvastatin 5 mg and fenofibrate 100 mg; simvastatin 10 mg and fenofibrate 100 mg; simvastatin 20 mg and fenofibrate 100 mg; simvastatin 40 mg and fenofibrate 100 mg; simvastatin 80 mg and fenofibrate 100 mg; simvastatin 5 mg and fenofibrate 110 mg; simvastatin 10 mg and fenofibrate 110 mg; simvastatin 20 mg and fenofibrate 110 mg; simvastatin 40 mg and fenofibrate 110 mg; simvastatin 80 mg and fenofibrate 110 mg; simvastatin 5 mg and fenofibrate 120 mg; simvastatin 10 mg and fenofibrate 120 mg: simvastatin 20 mg and fenofibrate 120 mg; simvastatin 40 mg and fenofibrate 120 mg; and simvastatin 80 mg and fenofibrate 120 mg; simvastatin 5 mg and fenofibrate 130 mg; simvastatin 10 mg and fenofibrate 130 mg simvastatin 20 mg and fenofibrate 130 mg; simvastatin 40 mg and fenofibrate 130 mg; simvastatin 80 mg and fenofibrate 130 mg; simvastatin 5 mg and fenofibrate 145 mg; simvastatin 10 mg and fenofibrate 145 mg: simvastatin 20 mg and fenofibrate 145 mg; simvastatin 40 mg and fenofibrate 145 mg; and simvastatin 80 mg and fenofibrate 145 mg.

13. (Previously Presented) The composition according to claim 10, wherein the HMG-CoA reductase inhibitor is atorvastatin.

14. (Previously Presented) The composition according to claim 13, wherein the atorvastatin is selected from the group consisting of crystalline atorvastatin calcium, amorphous atorvastatin calcium, crystalline atorvastatin magnesium, amorphous atorvastatin magnesium, a mixture of amorphous and crystalline atorvastatin calcium and a mixture of amorphous and crystalline atorvastatin magnesium.

15. (Previously Presented) The composition according to claim 13, wherein the atorvastatin is crystalline atorvastatin magnesium.

16. (Previously Presented) The composition according to claim 13 comprising a fixed dose combination selected from the group consisting of atorvastatin 5 mg and fenofibrate 100 mg; atorvastatin 10 mg and fenofibrate 100 mg; atorvastatin 20 mg and fenofibrate 100 mg; atorvastatin 40 mg and fenofibrate 100 mg; atorvastatin 80 mg and fenofibrate 100 mg; atorvastatin 5 mg and fenofibrate 110 mg; atorvastatin 10 mg and fenofibrate 110 mg; atorvastatin 20 mg and fenofibrate 110 mg; atorvastatin 40 mg and fenofibrate 110 mg; atorvastatin 80 mg and fenofibrate 110 mg; atorvastatin 5 mg and fenofibrate 120 mg; atorvastatin 10 mg and fenofibrate 120 mg: atorvastatin 20 mg and fenofibrate 120 mg; atorvastatin 40 mg and fenofibrate 120 mg; and atorvastatin 80 mg and fenofibrate 120 mg; atorvastatin 5 mg and fenofibrate 130 mg; atorvastatin 10 mg and fenofibrate 130 mg: atorvastatin 20 mg and fenofibrate 130 mg; atorvastatin 40 mg and fenofibrate 130 mg; and atorvastatin 80 mg and fenofibrate 130 mg; atorvastatin 5 mg and fenofibrate 145 mg; atorvastatin 10 mg and fenofibrate 145 mg: atorvastatin 20 mg and fenofibrate 145 mg; atorvastatin 40 mg and fenofibrate 145 mg; and atorvastatin 80 mg and fenofibrate 145 mg.

17. (Previously Presented) The composition according to claim 13 which further comprises a stabilizer capable of providing a microenvironment for atorvastatin having a pH of at least about 5.

18. (Previously Presented) The composition according to claim 13 which further comprises a stabilizer capable of providing a microenvironment for atorvastatin having a pH of at least about 6.

19. (Withdrawn) The composition according to claim 13 which further comprises a stabilizer selected from the group consisting of inorganic alkalizing compounds.

20. (Withdrawn) The composition according to claim 19, wherein the stabilizer is selected from the group consisting of metal salts, alkaline earth metal salts, talc and bentonite.

21. (Withdrawn) The composition according to claim 19, wherein the stabilizer is selected from the group consisting of calcium salts (calcium carbonate, calcium hydroxide, di calcium phosphate, tri calcium phosphate), magnesium salts (magnesium carbonate, magnesium hydroxide, magnesium silicate, magnesium aluminate, aluminum magnesium hydroxide), lithium salts (lithium hydroxide), potassium salts (potassium hydroxide) and sodium salts (sodium bicarbonate, sodium borate, sodium carbonate, sodium hydroxide).

22. (Withdrawn) The composition according to claim 13 which further comprises a stabilizer selected from the group consisting of organic alkalizing compounds.

23. (Withdrawn) The composition according to claim 22, wherein the stabilizer is selected from the group consisting of amines, amides and ammonium compounds.

24. (Previously Presented) The composition according to claim 22, wherein the stabilizer is selected from the group consisting of ammonia, ammonium lactate, ammonium bicarbonate, ammonium hydroxide, ammonium phosphate dibasic, mono ethanolamine, di ethanolamine, tri ethanolamine, tri hydroxymethylaminomethane, ethylenediamine, N-methyl glucamide, 6N-methyl glucamine, meglucamine, L-lysine and 2-amino-2-(hydroxymethyl)-1,3-propanediol.

25. (Previously Presented) The composition according to claim 17, wherein the stabilizer is 2-amino-2-(hydroxymethyl)-1,3-propanediol.

26. (Previously Presented) The composition according to claim 1, wherein the second composition comprises atorvastatin and from about 0.01% w/w to about 5% w/w of 2-amino-2-(hydroxymethyl)-1,3-propanediol.

27. (Previously Presented) The composition according to claim 1, wherein the first or the second composition further comprises acceptable excipients.

28. (Previously Presented) The composition according to claim 1, wherein the first composition comprises micronized crystalline fenofibrate.

29. (Currently Amended) The composition according to claim 1, wherein the first composition comprises ~~a solid solution of~~ fenofibrate dissolved in a vehicle comprising polyethylene glycol (PEG).

30. (Currently Amended) The composition according to claim 27, wherein the first composition comprises ~~a solid solution of~~ fenofibrate dissolved in a vehicle comprising polyethylene glycol 6000 (PEG 6000) and poloxamer 188.

31. (Previously Presented) The composition according to claim 27, wherein the first composition comprises lactose as a carrier.

32. (Withdrawn) The composition according to claim 27, wherein the first composition comprises magnesium stearate as a lubricant.

33. (Withdrawn) The composition according to claim 1, wherein the second composition comprises simvastatin and lactose as a carrier.

34. (Withdrawn) The composition according to claim 1, wherein the second composition comprises atorvastatin magnesium and mannitol as a carrier.

35. (Withdrawn) The composition according to claim 27, wherein the second composition comprises magnesium stearate as a lubricant.

36. (Previously Presented) The composition according to claim 27, wherein the second composition comprises starch as a disintegrant.

37. (Previously Presented) The composition according to claim 27, wherein the second composition comprises one or more antioxidants selected from the group consisting of ascorbic acid, citric acid and butyl hydroxyl anisole.

38. (Previously Presented) The composition according to claim 27, wherein the second composition comprises microcrystalline cellulose as a filler.

39. (Previously Presented) The composition according to claim 1, wherein the single solid dosage form is a two-layer tablet prepared by compressing the first composition in the form of granulate together with the second composition in the form of granulate

40. (Previously Presented) The composition according to claim 1, wherein the single solid dosage form is a two-layer tablet prepared by compressing the first composition in the form of granulate together with the second composition in the form of granulate having a protective coating.

41. (Previously Presented) The composition according to claim 1, wherein the single solid dosage form is a two-layer tablet prepared by compressing the first composition in the form of granulate together with the second composition in the form of entero-coated granulate.

42. (Previously Presented) The composition according to claim 1 containing not more than 0.5% atorvastatin in lactone form after storage at 40.degree. C. and 75% relative humidity for 1 month.

43. (Previously Presented) The composition according to claim 1 containing not more than 0.1% atorvastatin in lactone form after storage at 40.degree. C. and 75% relative humidity for 1 month.

44. (Previously Presented) The composition according to claim 1 containing not more than 0.05% atorvastatin in lactone form after storage at 40.degree. C. and 75% relative humidity for 1 month.

45. (Previously Presented) The composition according to claim 1 for the treatment of a subject suffering from atherosclerosis, hyperlipidemia, and/or hypercholesterolemia.

46. (Previously Presented) The composition according to claim 43 for the treatment of a human subject.

47. (Withdrawn) A method for preparing a tablet comprising a first solid composition containing fenofibrate as the active substance and second solid composition containing an HMG-CoA reductase inhibitor as the active substance, the first and the second composition being present in separate entities, which method comprises the steps of:i) preparing the first solid composition by dissolving fenofibrate in a vehicle and spraying the resulting liquid solution on a solid carrier in a controlled agglomeration process, optionally mixing the agglomerated particles with a lubricant, and mixing the agglomerated particles to form a granulate,ii) preparing the second solid composition by wet granulation, andiii) compressing the first and second compositions into a multilayer tablet, the first and second compositions being present in separate layers.

48. (Currently Amended) A single solid dosage form comprising a composition for oral administration comprising a fixed dose combination of a first solid composition containing fenofibrate ~~as the active substance~~ and second solid composition containing an HMG-CoA reductase inhibitor ~~as the active substance~~, wherein the first and the second compositions are present in separate layers ~~entities~~.

49. (New) A stable oral dosage form comprising:

(a) a first layer comprising fenofibrate, poloxamer, and polyethylene glycol; and

(b) a second layer comprising a statin selected from simvastatin, atorvastatin, and pharmaceutically acceptable salts thereof, wherein when the second layer includes simvastatin, at most 0.2% of it converts to the hydroxy acid form of simvastatin after storage of the dosage form for 1 month at 25°C and 60% relative humidity; and

when the second layer includes atorvastatin, at most 0.1% of it converts to the lactone form of atorvastatin after storage of the dosage form for 1 month at 40°C and 75% relative humidity.